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09/339,818 06/25/99 DAVIS

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EXAMINER

CRANE, J

ART UNIT

PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/339,818

Applicant(s)
Davis et al.

Examiner
L. E. Crane

Group Art Unit
1623

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ---3--- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on May, 22, 2000 (Election; IDS) -----
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-45 ----- is/are pending in the application.
- Of the above claim(s) 19-23, 35-36, 38-43 and 45 ----- is/are withdrawn from consideration.
- ☐ Claim(s) ----- is/are allowed.
- ☒ Claim(s) 1-18, 24-34, 37 and 44 ----- is/are rejected.
- ☐ Claim(s) ----- is/are objected to.
- ☐ Claim(s) ----- are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8 ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

Art Unit 1623

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5 No claims have been cancelled and no preliminary amendments filed as of the date of the instant Office action. An Information Disclosure Statement (IDS) filed May 22, 2000 has been received and entered.

Claims 1-45 remain in the case.

- 10 Applicant's election with traverse of Group I, claims 1-18, 24-34, 37 and 44 in Paper No. 7 is acknowledged. The traversal is on the grounds that the examiner has not established that a serious search burden exists and that therefore that the instant restriction is improper. Examiner respectfully disagrees. These arguments are not found persuasive because some of the instant claims (e.g. claims 1-2 and 6-15 17) are drafted using schematic diagrams which are generically defined by the claims to be cyclodextrin moieties and linking moieties. The complete absence of any well defined chemical formula representations of what applicant is claiming in most of the claims is deemed to render the instant claims so indefinite that devising a usable search statement is nearly impossible. In the claims where applicant has included chemical 20 structures are more useful in devising electronic structure search strategies, but appear to contain flaws (missing structural components) which make even these structures misleading. The complete absence of any well defined chemical formula representations of what applicant is 25 claiming in independent claims is deemed to render the instant claims so indefinite that devising a comprehensively accurate and usable search

Art Unit 1623

statement is nearly impossible. Therefore, the apparent impossibility of finding a reasonably precise description of the nature of the instant invention renders answer to the question of search burden obvious: the overall burden is indeterminate and therefore cannot possibly be met until
5 such time that applicant chooses to provide a more clearly and completely defined set of claims.

The requirement is still deemed proper and is therefor made FINAL *h/d*

10 Claims 19-23, 35-36, 38-43 and 45 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

15 Claims 1-18, 24-34, 37 and 44 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 4 and 5, the schematic diagrams representing repeating units of "1a, 1b or combinations thereof" are indefinite for two reasons:
20 i) the schematic diagrams do not provide complete information concerning the specific molecular interconnections which are required to understand with particularity the structures of the intended copolymers; and
ii) the term "polymer comprising" is incorrect when directed to a compound because it implies that there are structural variations not described in the claim. In addressing this rejection applicant is
25 encouraged to use properly enabled and complete chemical structures in place of the schematic figures, or alternatively, properly enabled and

Art Unit 1623

complete chemical structures of all starting materials in a product by process claim format.

In claim 1, line 5, the terms "C is a substituted or unsubstituted cyclodextrin monomer and A is a comonomer bound to the cyclodextrin" is
5 indefinite for the following reasons:

- i) the nature of the substituents have not been defined rendering the definition incomplete;
- ii) the specific attachment points apparently hinted at by the schematic representations of the cyclodextrin-A moieties have not been defined
10 rendering the definition incomplete; and
- iii) the comonomer "A" is not further defined in any way rendering the definition incomplete.

In claim 3, line 3, the chemical structure representing α -, β - or γ -cyclodextrin is incorrect because of a missing $-\text{CH}_2\text{-OH}$ group from the
15 nominally pentopyranose ring at the right end of the structure. Cyclodextrins are by definition cyclic oligohexoses and therefore do not contain any pentopyranose rings. The same problem reoccurs in claim 27.

In claim 3, lines 1-4, the term "cyclodextrin monomer," the chemical formula at line 3 and the Markush group members are technically
20 inconsistent. Did applicant intend the Markush preamble to read -- is selected from diradicals derived from the group consisting of --? If so, examiner suggests that the end of the claim should be amended by addition of the following proviso: -- with the proviso that the linkage-forming radicals are formed at the deoxygenated sites --. A similar
25 problem occurs in claims 4, 5, 28 and 29.

Art Unit 1623

In claim 6, lines 10-19, the listed Markush group members are not followed by appropriate punctuation (e.g. ", "). The same problem reoccurs in claim 30.

5 Claim 6 is internally inconsistent because some secondary amine functions are shown as protonated and with a positive charge, but the hydrazone equivalents ("HNNHC(O)-...") are not treated in a similar manner (e.g. -- -⁺H₂NNHC(O)- --). A similar inconsistency problem occurs when the "A" moiety has an imidazole moiety included therein (some are shown protonated and some are not). Also, the Markush group members are
10 lacking any indication of counter ions rendering the definition incomplete. The same problem reoccurs in claim 30.

In claim 7, the term "A is biodegradable or acid-labile" is functional language not easily translatable into specific chemical structures, thereby rendering the metes and bounds of the instant claim indefinite.

15 In claim 8, line 2, the term "crosslinked to a polymer" begs the question "how(?)" or more specifically, "with what included functionality(?)" or "with what type of crosslinking reagent interacting with which included functionality?" The same problem reoccurs in claim 13.

20 In claims 9 and 10, line 1, the term "at least one ligand is bound to the linear cyclodextrin copolymer" implies subject matter ("ligand") which is open to various interpretations. For example, cyclodextrins are known as ligands capable of complexing compounds within their cavities. Cyclodextrins are also known to possess large number of hydroxy moieties
25 which can cooperatively render the cyclodextrin a ligand for metals, metal

Art Unit 1623

complexes, and/or metal ions capable of coordination simultaneously with one or more hydroxyl moieties. Or, the claim may be referring to some appended "ligand" substituent the chemical character of which has not been defined in the claim. Appropriate clarification is respectfully
5 requested. The same problem reoccurs in claims 14, 15 and 31.

In claim 11, lines 1-2, the term "wherein at least one cyclodextrin monomer C is oxidized" is indefinite for failure to specify what is meant by the term "oxidized." It is plain that the cyclodextrin already include hydroxyl moieties which represent partially oxidized carbon substituents
10 so the noted term may be deemed to be entirely superfluous.

Alternatively, applicant may have intended a specific additional oxidation product of which there are numerous possibilities (e.g. in β -cyclodextrin there are 21 primary and secondary hydroxyl groups each of which may become the object of further oxidation). For these reasons, a reading of
15 the noted claim does not permit the ordinary practitioner to be able to distinguish between these alternatives. Applicant is respectfully requested to resolve the noted confusion. The same problem reoccurs in claims 16 and 17.

In claim 12, the "monomer" is -- derived from a cyclodextrin -- but
20 cannot by definition be an independent cyclodextrin compound. A similar problem reoccurs in claim 26.

In claim 16, line 1, the term "substantially" is per se indefinite and its deletion is respectfully requested.

In claim 18, the term "therapeutic composition" is non-standard
25 terminology. Did applicant intend the format to be -- A pharmaceutical composition comprising a cyclodextrin oligomer of any one of claims 19,

Art Unit 1623

20, 21, or 22, a (second active ingredient) and a pharmaceutically acceptable carrier.--? If so applicant is respectfully requested to substitute or amend as appropriate, and to make the claim complete to specify the additional active ingredient ("therapeutic agent") or a Markush
5 group from which it may be selected.

In claim 24, the entire process is described in functional language using schematic representations of the products. The metes and bonds will become reasonably clear when applicant provides real molecular starting materials in the form of complete chemical structures (with "the
10 same or different leaving group[s] " specified !!) within the instant claim or a replacement therefore.

In claim 25, applicant again resorts to schematic representations. Complete molecular structures are respectfully requested. In addition, the noted claim lacks proper terminal punctuation, and lacks punctuation to
15 separate structures (IVa) and (IVb). Claims 32-34 by their dependence on claim 25 inherently have the same problem.

Claims 33 and 34 both lack punctuation to separate the chemical structures therein and also lack terminal punctuation.

Claim 37 by its reliance on terms already noted as functional and therefore indefinite has the same problems noted above in rejections
20 directed to the terms "ligand" and "oxidized."

Claim 44 is directed to a "method of treatment" but is incomplete for failure to specify what disease or other medically treatable condition is being treated.

Art Unit 1623

Claims 1-18, 24-34, 37 and 44 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 1-18, 24-34, 37 and 44 the use of generic terminology like "comonomer" and "cyclodextrin copolymer" implies a far wider scope of subject matter than applicant has enabled within the instant specific embodiments. Applicant is therefore respectfully requested to more nearly limit the scope of the instant claims to the scope of the enabled embodiments.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Art Unit 1623

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

5 Claims 1-18 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-23 and 45 of copending Application No. 09/203,556 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the '556 application is so broadly and indefinitely defined that some, if not all, of
10 the subject matter of the instant application is included within the vast scope of the '556 claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15 Claims 1-18 and 44 of this application conflict with claims 19-23 and 45 of Application No. 09/203,556 . 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is
20 required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

25 The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

Art Unit 1623

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

10 (e) the invention was described in a patent granted on an application to another filed in the United States before the invention thereof by applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Claims 1-2, 7-18, 24, 31, 37 and 44 are rejected under 35 U.S.C. §102(e) as being anticipated by Bachmann et al. '768 (PTO-1449 ref. AA).

15 Applicant is referred to the '768 patent's abstract which refers to "biomedical articles," to column 3, lines 35-39, to column 5, lines 32-36, to column 7, lines 1-3, and to column 7 lines 19-23 and associated explanatory text as containing subject matter which reads directly on the instant claims including "oxidized" cyclodextrins as being an obvious variation following from contact with hydrogen peroxide in the presence
20 of metal ions, a mixture well known to generate hydroxyl radicals, a notoriously well known oxidizing agent.

After review of the references presently of record, it appears that some of the claims (3-6, 25-30 and 32-34) are free of the prior art. Therefore, examiner concludes that claims 3-6, 25-30 and 32-34 would
25 be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Art Unit 1623

The disclosure is objected to because of the following informalities:

At pages 42 and 44, last line of both, the structural representations incorporating a schematic "cyclodextrin" appear to contain pentavalent carbons. The same problem reoccurs at p. 48. Applicant is respectfully
5 requested to amend the instant use of schematic formulas to avoid this obvious technical error.

Appropriate correction is required.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes
10 that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not
15 commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30,
20 November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592 .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639 . The examiner can normally be
25 reached between 9:30 AM and 5:00 PM, Monday through Friday.

.Art Unit 1623

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose
5 telephone number is 703-308-1235.

LECrane:lec
07/26/00


L. Eric Crane
Patent Examiner
Group 1600